# SUPPORT FOR THE AMENDMENTS

Claims 25-36 have been added.

Support for new Claims 25-36 is provided by original Claims 1-6, previously pending Claims 1-6 and 19-24, as well as the specification at, for example, page 3, lines 16-27 page 5, lines 15-17.

No new matter has been entered by the present amendments.

## **REMARKS**

Claims 1-36 are pending in the present application.

At the outset, Applicants wish to thank Examiner Corbin for the helpful and courteous discussion with their undersigned representative on December 9, 2008. During this discussion various amendments and arguments in traverse of the outstanding rejections, supported by experimental evidence, were discussed. The content of this discussion is reflected in the amendments and comments presented herein. Reconsideration of the outstanding rejections is requested.

The rejection of Claims 1-24 under 35 U.S.C. §103(a) over Okawa et al (US 2002/0022062) is traversed.

In the outstanding Office Action the Examiner has maintained his allegation that Okawa et al render the claimed invention obvious. In maintaining the rejection over Okawa et al, the Examiner states that he has fully considered the arguments filed on June 25, 2008, but the "newly claimed ration of '5 to 15' does not patentably distinguish over either primary reference. In this regard, application is referred to Ex. 9 of Okawa et al wherein applicant's claimed ratio is disclosed." Applicants disagree with this allegation by the Examiner with respect to the claimed ratio, as well as the allegation that the claimed invention would be obvious.

Applicants submit that, as set forth in the Declaration under 37 C.F.R. §1.132 executed by Tatsuya Kusaura ("the Kusaura Declaration") **submitted herewith**, Example 9 of Okawa et al actually has a ratio of hydroxycarboxylic acid content to chlorogenic acid content corresponding ratio is 19.8.

Specifically, paragraph 7 of the Kusaura Declaration provides an explanation of the calculation of the (b) Vitamin C/(a) Chlorogenic acid found in the coffee bean extract used in Example 9 of Okawa et al:

7. The coffee bean extract used in Example 9 of Okawa et al ("Flavor Holder FH1041" from T. Hasegawa Co. Ltd.) contains 28.1 wt% of chlorogenic acid. The chlorogenic acid content in FH1041 and the other disclosed coffee bean extracts is calculated as follows:

In paragraph [0021], Okawa et al disclose the preparation of the extracts from coffee beans used in their Examples. Specifically, paragraph [0021] discloses:

From "Flavor Holder FH1041" (trade name of a food additive; product of T. Hasegawa Co., Ltd.; Coffee Bean Extract 3), an eluate was obtained using a cationic exchange column (for example, "SK-1B", trade name; product of Mitsubishi Chemical Co., Ltd.), followed by concentration into Coffee Bean Extract 4. Caffeine was extracted from the column and the extract was added to the coffee bean extract for ingredient adjustment, whereby Coffee Bean Extracts 1 and 2 were prepared.

In paragraph [0022], Okawa et al disclose the "dry solid contents of Coffee Bean Extracts prepared by the above-described process and amounts of chlorogenic acid and caffeine contained in them are shown in Table 1". Table 1 (below) reflects Table 1 of Okawa et al and has been expanded to include the amount of chlorogenic acid and caffeine in the extract:

Table 1

Table I	Dry solid content %	Chlorogenic and caffeine in Extract	Chlorogenic / caffeine ratio	Chlorogenic acid % in Extract	Caffeine % in Extract		
	Content %	Total %	Ratio	%	%		
Extract 1	71%	51%	1.2	27.8%	23.2%		
Extract 2	58%	39%	2.5	27.9%	11.1%		
Extract 3	53%	34%	4.8	28.1%	5.9%		
Extract 4	48%	29%	28.0	28.0%	1.0%		

In Table 1 above, the content of the chlorogenic acid in the extract (using Extract 3 as an example) is calculated as follows:

(4.8)/(4.8+1.0)\*34%= chlorogenic acid % in extract

Application Serial No. 10/518,372 Reply to Office Action of September 10, 2008

Thus, looking at Example 9 (paragraph [0045]) of Okawa et al, it is possible to calculate the ratio of hydroxycarboxylic acid content to chlorogenic acid content as follows:

Vitamin C (ascorbic acid) 2000mg (4% in drink)

Flavor Holder (FH1041) 360mg

→Chlorogenic acid content **28.1%** 101mg (<u>0.202% in drink</u>)

total amount 50mL (b) Vitamin C / (a) Chlorogenic acid = 19.77

More precisely, the ratio of hydroxycarboxylic acid (Vitamin C) to chlorogenic acid in the compound of Example 9 is calculated as:

$$2000 \text{mg} / (360 \text{mg x } 0.281) = 2000/101.16 = 19.77$$

This ratio does not fall within the claimed range (5 to 15).

It should also be noted that, as shown in Table 1 of the Kusaura Declaration, the same ratio would be achieved regardless of whether coffee bean extract 1, 2, or 4 were used in Example 9 in place of coffee bean extract 3.

The fact that Okawa et al fail to disclose or suggest the claimed ratio of hydroxycarboxylic acid content to chlorogenic acids represents a critical defect in the disclosure of Okawa et al. To demonstrate the criticality of the claimed ratio range of 5 to 15, Applicants refer to paragraphs 8-9 of the Kusaura Declaration.

8. To demonstrate the criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content is within the range of 5 to 15, the following procedure was followed:

### (a) Experiments

Experiments 2 to 5: Products with (b)/(a) ratio within the

range of 5 - 15

Experiments 1 and 6 to 8: Reference Products with (b)/(a) ratio outside the range of 5 - 15

Exp. 1: Comparative Example 6 of the present application

Exp. 2: Example 7 of the present application

Exp. 3: Example 3 of the present application

Exp. 4: currently added (a composition of the present invention)

Exp. 5: currently added (a composition corresponding to Okawa with (b)/(a) ratio of 15)

- Exp. 6: currently added (a composition corresponding to the invention expect that (b)/(a) ratio was 19.8)
- Exp. 7: Example 9 of Okawa ((b)/(a) = 19.8)
- Exp. 8: Comparative Example 3 of the present application

## (b) Evaluation

- (i) Dreg formation (25°C, 24 hours)
- Evaluation method and criteria were the same as described at page 8, lines 14-21 of the specification for the above-identified application.

### Rating

- 1: No dreg formation was observed.
- 2: Dreg formation was observed a little.
- 3: Dreg formation was observed definitely
- (ii) Storage stability (long term stability, suggested at page 14, lines 10-11 of the specification for the above-identified application) Evaluation was performed after storage for 7 days at 60°C.

#### Evaluation criteria:

color darkened : 3 color slightly darkened : 2 color not changed : 1

(iii) Taste, Astringency, Bitterness, and Foreign taste

Evaluation methods were the same as described at page 7, line 32 to page 8, line 2 of the specification for the above-identified application.

Evaluation criteria of "Taste" was the same as described at page 8, lines 6-13 of the specification for the above-identified application.

#### Evaluation criteria of "Astringency"

Astringency is felt very strongly	: 4
Astringency is felt strongly	: 3
Astringency is felt	: 2
Astringency is slightly felt	: 1
Astringency is not felt at all	: 0

#### Evaluation criteria of "Bitterness"

Bitterness is felt very strongly	: 4
Bitterness is felt strongly	: 3
Bitterness is felt	: 2
Bitterness is slightly felt	: 1
Bitterness is not felt at all	: 0

# Application Serial No. 10/518,372 Reply to Office Action of September 10, 2008

Evaluation criteria of "Foreign taste"

Foreign taste is felt very strongly : 4
Foreign taste is felt strongly : 3
Foreign taste is felt : 2
Foreign taste is slightly felt : 1
Foreign taste is not felt at all : 0

9. Table 2 shows the results obtained from these experiments:

Application Serial No. 10/518,372 Reply to Office Action of September 10, 2008

8	Com.Ex. 3	in the present	annlication		375 mg (*5)	8 mg	52 mg	1,7	2000 mg		ı		2000 mg	38.6	91.625 g	4.4 g	1.5 g		0.10	1.5	3 69		co	c.	, -	- c	, -	-
	Com	in the	ilane	200	375 r	8	52		200				200	**	91.6	4.	-	<u> </u>	-		(0.					-		
7		Example 9	in Okawa		360 mg (*5)	14 mg	101 mg	1/7	1	ı	1	2000 mg	2000 mg	18.1	50 g in total		,	11 a		3.0	0.80	2	6	3 0	1 0		5 7	~
9					235 mg (*5)	10 mg	70 mg	1.17	350 mg	686 mg	350 mg		1386 mg	19.8	97.365 g		150	5	-	5 0	3.5	00.	c	7 6	7	- 0	2	-
8	,				475 mg (*5)	19 mg	133 mg	1/7			1	2000 mg	2000 mg	45	50 a in total			1,0	6-	, 0	3.0	24.3		5	) -  -	ח	3	_
	-	-			235 mg (*5)	10 mg	70 mg	1/7	350 mg	350 mg	350 mg		1050 mg	16	97.365 n	6000	1 7 7	B 0.1		0.1 g	3.4	1.50			0	0	0	_
·	ر د د	Example 3	in the present	application	235 mg (*5)	10 mg	20 mg	1/1	050 ma	300 mg	0.00 mg	81	- BUU WU	11.6	07.0660	6000.26		1.5 g	1	0.1 g	3.8	1.38		0	0	0	0	_
,	7	Example 7	in the present	application		00	140 mg	177	200	6111 OC 7	1 00 mg	4 20 Trig	- 000	SIII 000	3 8	90.63 y		1.5 g		0.1 g	4.5	1.55		_	0	0	1	
	_	Com.Ex. 6	in the present	application	360 mg (*5)	7.7	Bus C.I.	105 mg		300 mg	1 6	Sn mg	30 m g	South Ind	D.4	97.69.9		1.5 g	-	0.1 g	3.0	1.47		3	-	2	က	     
	Experiment No.		corresponding to:		(Material comprising	chlorogenic acid)	Isochlorogenic acids	(a) Total chlorogenic acids Isochlorogenic acids	contentratio	Citric acid	Malic acid	Sodium citrate		(b) Total hydroxycarboxylic acid	(B)(a)	(c) water	Apple juice (*2)	Fructose-glucose (*4)	Sucrose	Perfume	Ηū	Q, ix	< Evaluation >	Taste	Actrionappov	Difference	Foreign taste	mom usining

Rating of Storage stability: 3: color darkened 2: color slightly darkened 1: color not changed	
Rating of Dreg formation: 3: observed definitely 2: observed a little 1: no dreg was observed	
Rating of Taste, astringency, bitterness, and foreign taste: 4 : felt very strongly 3 : felt strongly 2 : felt 1 : slightly felt 0 : not felt at all	
*2 Aomori Apple Juice, 5-fold condensed (malic acid content 2.5%) *4 Joint Association of Agricultural Cooperatives of Ehime *5 Raw coffee beans extract *8 Evaluation after storage for 7days at 60 °C	

On the basis of the results demonstrated in paragraph 9 of the Kusaura Declaration, the declarant concluded:

10. The data above clearly illustrates the criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content within the range of 5 to 15. Specifically, the data above demonstrate that when the weight content of the ingredient (b) was higher than 15 times the weight of the ingredient (a) (experiment numbers 6-8), the beverage resulted in an overly acid flavor, rendering the beverage unfit for long-lasting drinking. When the weight content of hydroxycarboxylic acids (of ingredient (b)) was lower than 5 times the weight of the ingredient (a) (experiment number 1), the beverage exhibited astringency, bitterness or foreign taste. The criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content within the range of 5 to 15 is *unexpected*.

Applicants submit that disclosure and examples of Okawa et al fail to disclose or suggest the presence of a hydroxycarboxylic acid in a quantity ranging from 5 to 15 times the weight content of ingredient (a). The Examiner is reminded that Applicants can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims... In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Applicants submit that this burden has been met by the submission of the Kusaura Declaration.

For point of reference, Applicants submit that the criticality of the lower threshold limit of 5 is clearly demonstrated by referring to Experiment Nos. 1 and 2 (Comparative Example 6 and Example 7, respectively, as illustrated in Table 2 (page 10) and Table 1 (page 9) of the specification). Experiment Nos. 1 and 2 demonstrate that when the (b)/(a) ratio is below the claimed threshold of 5, the resulting beverage is worse in almost every measured

evaluation, including a poorer taste, astringency, bitterness, foreign taste, and storage stability.

With respect to the upper threshold limit of 15, reference is made to Experiment Nos. 3-8 of the Kusaura Declaration. Immediately evident from Experiment Nos. 3-5 (all meeting the required (b)/(a) ratio limits) as compared to Experiment Nos. 6-8 (all exceeding the (b)/(a) limit of 15) when the weight content of the ingredient (b) was higher than 15 times the weight of the ingredient (a) (experiment numbers 6-8), the beverage resulted in an overly acid flavor, rendering the beverage unfit for long-lasting drinking.

In view of the foregoing, Applicants submit that <u>Okawa et al</u> do not render the presently claimed invention obvious.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 1-24 under 35 U.S.C. §103(a) over <u>Suzuki et al</u> (EP 1 186 297) is traversed.

Applicants submit that <u>Suzuki et al</u> is equally as vague of a disclosure as <u>Okawa et al</u>. In other words, <u>Suzuki et al</u> is, at best, generic to the claimed invention. However, there is no specific disclosure or suggestion in <u>Suzuki et al</u> of the composition as defined in the claimed invention, much less any appreciation for the criticality of the ratio of (b)/(a). <u>Suzuki et al</u> merely describes physiological effects of its beverage and thus offers no disclosure or suggestion with respect to taste or stability of a beverage. As previously set forth, a beverage is generally required to have many properties designed to generate good taste and longlasting stability. There a large number of factors need to control such properties. The difference between the claimed invention and the disclosure of <u>Suzuki et al</u> (i.e., the range of ratios of (b)/(a)) does not represent mere optimization.

Indeed, above Applicants have clearly evidenced the criticality of the claimed ratios of (b)/(a) as supported by the Kusaura Declaration submitted herewith. In paragraph 11 of

the Kusaura Declaration, the declarant states:

Further, this result would not be predicated from the disclosure of Suzuki et al (EP 1 186 297), which only discloses the possibility of the presence of chlorogenic acid, generically discloses the content of chlorogenic acid, generically discloses the possibility of a hydroxycarboxylic acid, and generically discloses the content of the hydroxycarboxylic acid. Suzuki et al does not offer any guidance of a ratio of hydroxycarboxylic acid content to chlorogenic acid content ranging from 5 to 15. More importantly, Suzuki et al fails to provide any suggestion of the beneficial results flowing from this specific ratio

as demonstrated above.

Applicants submit that the experimental data set forth in the Kusaura Declaration demonstrates the criticality of the claimed ratio of (b)/(a). This demonstration is sufficient to rebut even a prima facie case of obviousness (In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)). As such, absent Applicant's disclosure the artisan would not be led to expect the superior results flowing from the specifically claimed range of ratios of (b)/(a) as

Applicants request withdrawal of this ground of rejection.

established by the Kusaura Declaration and explained above.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon

Customer Number 22850

Tel: (703) 413-3000 Fax: (703) 413-2220

(OSMMN 08/03)

Vincent K. Shier, Ph.D. Registration No. 50,552